# Conducting Research Outside of the U.S.

The IRB will review all international research utilizing human participants to assure adequate provisions are in place to protect the rights and welfare of the participants.

Approval of research is permitted if “the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46.”

All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.

The IRB must receive and review the foreign institution or site’s IRB review and approval of each study prior to the commencement of the research at the foreign institution or site.

For Federally funded research, approval of research for foreign institutions or sites “engaged” in research is only permitted if the foreign institution or site holds an Assurance with OHRP and local IRB review and approval is obtained.

Approval of research for foreign institutions or sites “not engaged” in research is only permitted if one or more of the following circumstances exist:

* When the foreign institution or site has an established IRB/IEC, the Investigator must obtain approval to conduct the research at the "not engaged" site from the site’s IRB/IEC or provide documentation that the site’s IRB/IEC has determined that approval is not necessary for the Investigator to conduct the proposed research at the site.
* When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.
* IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance site’s IRB/IEC determination, or letter of cooperation, as applicable.
* It is the responsibility of the main site Investigator and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.
* It is the responsibility of the main site Investigator and the foreign institution or site to confirm the qualifications of the Researchers and Research Staff for conducting research in that country(ies).
* It is the responsibility of the main site Investigator and the foreign institution or site to ensure that the following activities will occur.
  + Initial review, continuing review\*, and review of modification
  + Post-approval monitoring
  + Handling of complaints, non-compliance and unanticipated problems involving risk to subjects or others.

The IRB will not rely on a local ethics committee that does not have policies and procedures for the activities listed above.

* It is the responsibility of the main site Investigator and the foreign institution or site to notify the IRB promptly if a change in research activities alters the performance site’s engagement in the research (e.g., performance site “not engaged” begins consenting research participants, etc.).
* The IRB will consider local research context when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted, including knowledge of local laws and cultural context.
* In the case where there is no local IRB review the IRB may require an expert consultant, either from the local country where the research is conducted or from an international organization, with the expertise or knowledge required to adequately evaluate the research in light of local context.
* The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document which must be provided by the Investigator, with the credentials of the translator detailed in the IRB application or amendment form. Verification of the back translation should be made available for the IRB file.

## Monitoring of Approved International Research *(Best Practice)*

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations.

When the IRB and a local ethics committee will both be involved in the review of research, there is a plan for coordination and communication with the local ECs.

The IRB will require documentation of regular correspondence between the main site Investigator and the foreign institution or site and may require verification from sources other than the main site Investigator that there have been no substantial changes in the research since its last review.

\* Based on each site IRB determination if continuing review of research requirements in accordance with §46.109(f )